

**PLUS WHITE EXTRA WHITENING- sodium monofluorophosphate gel, dentifrice
CCA Industries, Inc.**

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

Plus White Extra Whitening Gel

Active Ingredient

Sodium Monofluorophosphate 0.83% (0.11% w/v fluoride ion)

Purpose

Anticavity Toothpaste

Uses

Aids in the prevention of dental cavities.

Warnings

If more than used for brushing is accidentally swallowed, get medical help or contact a Poison Control Center right away.

Keep out of the reach of children under 6 years of age.

Directions

- Adults and children 2 years and older
- Brush teeth thoroughly, after each meal, or at least twice a day, or as directed by a dentist or physician
- instruct under 6 years of age in good brushing and rinse habits (it minimizes swallowing), and only use a pea size amount.
- Children under 2 years ask a dentist or physician

Inactive ingredients Sorbitol, Hydrated Silica, Glycerin, Water (Purified), PEG 32, Flavor, Sodium lauryl Sulfate, PVM/MA Copolymer, Flavor, Cellulose Gum, Trisodium Phosphate, Sodium Phosphate, Sodium Saccharin, Blue 1, yellow 10

Questions or comments? Call Toll Free 1-800-595-6230

- www.pluswhite.com

Principal Display Panel - Tube 3.5 oz

Plus+White

Extra Whitening Gel TOOTHPASTE

Net Wt 3.5 oz (100G) - Fluoride Anticavity Toothpaste

For best results squeeze tube from bottom



**FIGHTS STAINS + PROTECTS
FOR SUPERIOR WHITENING!**

**Specially Formulated with
StainGuard® to Remove:**

- **Coffee** • **Tea**
 - **Wine** • **Tobacco**
- & Other Food Stains!**

- ▶ **Helps Remove Plaque to Control Tartar**
- ▶ **Fights Cavities**

Active Ingredient

Sodium monofluorophosphate 0.83% (0.11% fluoride ion).....Anticavity toothpaste
Use Aids in the prevention of dental cavities.

Warnings • **Keep out of reach of children under 6 years of age** • If more than used for brushing is accidentally swallowed, get medical help or contact a Poison Control Center right away.

Directions Adults and children 6 years of age and older: Brush teeth thoroughly, preferably after each meal or at least twice a day, or as directed by a dentist or doctor. Instruct children under 12 years of age in good brushing and rinsing habits (to minimize swallowing). Supervise children as necessary until capable of using without supervision. Children under 6 years of age: Do not use unless directed by a dentist or doctor.

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Mfd. in the USA, 65 Challenger Road Ridgefield Park, NJ 07660 USA
240144 TB27237-02 1-800-595-6230



PLUS WHITE EXTRA WHITENING

sodium monofluorophosphate gel, dentifrice

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:6 1543-1606
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SODIUM MONOFLUOROPHOSPHATE (UNII: C810JCZ56Q) (FLUORIDE ION - UNII:Q80VPU408O)	FLUORIDE ION	0.83 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
GLYCERIN (UNII: PDC6A3C0OX)	
POLYETHYLENE GLYCOL 1450 (UNII: OJ4Z5Z32L4)	
WATER (UNII: 059QF0K00R)	
HYDRATED SILICA (UNII: Y6O7T4G8P9)	
COPOVIDONE K25-31 (UNII: D9C330MD8B)	
TRISODIUM DIPHOSPHATE (UNII: AR70GW33N1)	

SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
CARBOXYMETHYLCELLULOSE SODIUM (UNII: K679OBS311)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
SORBITOL (UNII: 506T60A25R)	
SODIUM PHOSPHATE, MONOBASIC (UNII: 3980JIH2SW)	

Product Characteristics

Color	green	Score	
Shape		Size	
Flavor	MINT	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:61543-1606-3	1 in 1 CARTON	01/31/2018	
1		100 g in 1 TUBE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part355	01/31/2018	

Labeler - CCA Industries, Inc. (106771041)

Registrant - Sheffield Pharmaceuticals LLC (151177797)

Establishment

Name	Address	ID/FEI	Business Operations
Sheffield Pharmaceuticals LLC		151177797	manufacture(61543-1606)